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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,484	09/27/2004	Yasuaki Ito	62236(46342)	5324

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EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

18

Office Action Summary	Application No. 10/509,484	Applicant(s) ITO ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 18 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 18 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 11 and 18 have been amended, claims 1-10, 12-17 and 19-45 have been cancelled and claims 46-49 have been added as requested in the amendment filed on August 28, 2006.

Following the amendment, claims 11, 18 and 46-49 are pending in the instant application.

Claims 11, 18 and 46-49 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on August 28, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 11, 18 and 46-49 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record specifically articulated in section 5 of Paper mailed on May 26, 2006. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect. Therefore, the instant

Art Unit: 1649

claimed method of screening a compound that changes the binding properties of that protein lacks practical utility in currently available form.

Applicant traverses the rejection on the premises that the specification discloses that the instant TGR7 of SEQ ID NO: 4 is activated by β -alanine (bottom at p. 5 of the Response), which is considered to be an inhibitory neurotransmitter, and further, that “TGR7 is specifically expressed in neurons of dorsal root ganglion (DRG), which mediates the transmission of pain or itch” (top at p. 6). Applicant further refers to publication of Shinohara et al, 2004, which demonstrate that “TGR7 mRNA is co-expressed with a purinergic receptor (P2X3) and a vanilloid receptor (VR1)”. Applicant states that “one skilled in the art readily appreciate that TGR7 regulates a function of the DRG, a sensory transmittance via β -alanine” (middle at p.6). Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

To clarify the Examiner’s position, there is no argument that the instant known protein of SEQ ID NO: 4 could represent a GPCR, TGR7, which is activated by β -alanine. However, this alone cannot support a specific and substantial credible utility of the method of identifying a compound that changes the binding properties of TGR7 and β -alanine because the instant specification fails to teach the significance of this process. There appears to be no reference to any physiological condition that would be specifically regulated by this particular TGR7. If a skilled practitioner followed the protocol and practiced the claimed method to assay the binding between TGR7 and β -alanine in the presence of a compound, what would be the conclusion of finding a difference in binding? Is this a compound that is useful to treat a specific pathological condition or would the administration of the compound acerbate the disease?

Further, Example 6 at pp.99-100 of the instant specification discloses a pattern of tissue distribution of TGR7 with the highest concentration in dorsal root ganglion, “which is the passing point of all sensory information from the peripheral nerves”. Based on this disclosure, one skilled in the art would reasonably conclude that the instant TGR7 of SEQ ID NO: 4 could be involved in sensory transmission, “such as tactile sense, pressure sense, warm sense, cold sense, pain sense, kinesthetic sense, deep pain etc.” (top at p.100 of the instant specification); however, at present its specific role in any of these processes remains unknown.

Applicant’s reference to the post-filing document of Shinohara et al., 2004, cannot support practical utility of the instant invention because it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. The instant specification, as filed, asserts the utility of the claimed method as useful to identify “a therapeutic agent for sensory abnormality such as pain and itch” (middle at p.6 of the Response); however, there is no evidence of record presented at the time of filing to support this assertion.

The Court in *Brenner v. Manson* held that “[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” *Id.* at 534-35, 148 USPQ at 695.

§101 requires a utility that is “substantial”, i.e., one that provides a specific benefit in currently available form *Brenner*, 383, U.S. at 534-35, 148 USPQ at 695. *Brenner*’s standard has

Art Unit: 1649

been interpreted to mean that “vague, general disclosures or arguments of “useful in research” or “useful as building blocks of value to the researcher” would not satisfy §101. See *Kirk*, 376 F. 2d at 945 153 USPQ at 55 (interpreting *Brenner*).

Thus, for reasons of record in the previous communication from the office and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

6. Claims 11, 18 and 46-49 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 11, 18, as amended and new claims 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention essentially for reasons of record in section 10 of Paper mailed on May 26, 2006.

Specifically, claims 11, 18 and 46-49 are incomplete for omitting an essential conclusion step. Applicant is advised that unless specifically recited, step (c) “comparing cases (i) and (ii)” is meaningless with respect to screening a test compound. It is not obvious and cannot be determined from the claims or the instant specification, as what parameter, factor or data point is supposed to be analyzed or compared.

Art of record

8. The art of record that discloses a polypeptide with 100% identity to the instant polypeptide of SEQ ID NO: 4 is as follows:

WO-01/66750 (2001);

WO-01/70814 (2001);

WO-01/57085 (2001);

WO-01/48188 (2001);

WO-01/36471 (2001) and

WO-01/83748 (2001); all presented in IDS submitted on 09/27/2004.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Art Unit: 1649

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870.

The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

October 10, 2006